



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-1548]

Invitation to Participate in Account Management Pilot for the Import Trade Auxiliary Communication System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it intends to conduct a pilot program to test and evaluate a new Import Trade Auxiliary Communication System (ITACS) Account Management function. Participation will be needed from a small group of Filers, Importers of Record, and Consignees, who will use the new ITACS Account Management function and provide feedback to FDA. FDA is inviting individual firms that wish to participate in this pilot program to submit participation requests via email.

DATES: To be considered for participation in this ITACS pilot, please send an email with the subject line "ITACS Pilot Participation Request" by [INSERT DATE 14 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit pilot participation request emails to FDA's ITACS Support at itacssupport@fda.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Sandra Abbott, Division of Compliance Systems, Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20852-1740, 301-796-3240, itacssupport@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

ITACS currently provides the import trade community with four functions: (1) The ability to check the status of FDA-regulated entries and lines, (2) the ability to submit entry documentation electronically, (3) the ability to electronically submit the location of goods availability for those lines targeted for FDA physical examination, and (4) the ability to check the estimated laboratory analysis completion dates. No user login accounts are necessary to access these functions; all that is necessary is a valid customs entry number that has been successfully transmitted to FDA. FDA has developed, and wishes to test, an ITACS user account management function.

II. Description and Conditions of the Pilot Program

The purpose of this pilot is to test and evaluate a new ITACS account management function.

This pilot will not impact the availability of current functionality of ITACS. Rather, it will provide FDA and a small group of volunteers with the opportunity to test expanded functionality of ITACS, specifically the use of user login accounts. User login accounts enable FDA to distribute Notices of FDA Action to users electronically via email (rather than regular mail) and enable users to download Notices of FDA Action from within ITACS. User login accounts also allow users to view in ITACS the details of specific information requests, which are currently delivered via hard copy Notices of FDA Action. Implementation of user login accounts would also allow for potential future ITACS enhancements, requested by the import trade community, that require user authentication.

Pilot participants should be prepared to commit to: (1) Attending a kickoff training session, using the new functionality, (2) providing real-time feedback, and (3) participating in any followup meetings FDA deems necessary over the course of the pilot period. Pilot participants should also be willing to receive their Notices of FDA Action electronically in lieu of FDA distribution of paper Notices of FDA action.

III. Duration

FDA currently anticipates the pilot to begin in [INSERT MONTH AND YEAR OF DATE 30 CALENDAR DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] and to last through [INSERT MONTH AND YEAR OF DATE 120 CALENDAR DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. However, these dates are subject to change. A more definitive schedule will be determined after FDA has selected volunteers. FDA will contact selected volunteers via email within 2 weeks of the closure of the solicitation period.

IV. How to Apply for Participation in the Pilot

To be considered for participation in this ITACS pilot, please send an email with the subject line “ITACS Pilot Participation Request” to itacssupport@fda.hhs.gov by [INSERT DATE 14 CALENDAR DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Please limit participation requests to one individual per firm at the corporate level. That person should be a high-ranking individual within the firm who could have the capability to create and manage ITACS accounts for other users at different locations within the same firm. FDA expects to select nine or fewer participants for this pilot program.

Please include the following information in your pilot participation request email:

- Your name, position, and contact information including email;

- your firm's name and address; and
- your firm's role in the importation of FDA-regulated entries (Filer, Importer of Record, Consignee, or any combination thereof).

FDA will contact volunteers selected for participation in the pilot program via email within 2 weeks of the closure of the solicitation period.

Dated: June 17, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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